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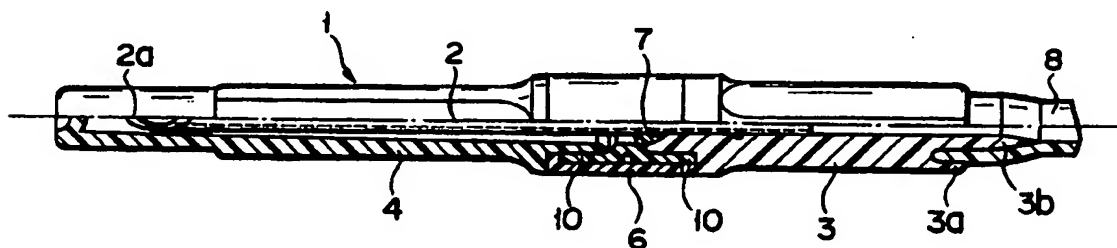
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W-8000 München 5(DE)(54) **Medical needle device and medical apparatus having the same.**

(57) A medical needle device includes a hollow needle (2), a hub (3) for supporting the base of the hollow needle (2), and a protector (4) for covering and sealing the hollow needle (2) projected from the hub (3). The protector (4) and the hub (3) are liquid-tightly integrated with each other by a coupler (5). The coupler (5) is provided with a breakable thin portion (9) and when this thin portion (9) of the coupler (5) is broken off, the protector (4) and the

hub (3) can be separated from each other. A pipe-like member (6) is provided around the coupler (5) and fixed to the protector (4). After the thin portion (9) of the coupler (5) is broken off, the pipe-like member (6) can be fitted onto that portion of the coupler (5) which remains on the hub (3), to thereby connect the protector (4) and the hub (3) to each other.

**FIG. 1****EP 0 419 880 A1**

MEDICAL NEEDLE DEVICE AND MEDICAL APPARATUS HAVING THE SAME

The present invention relates to a medical needle device of the disposable type and a medical apparatus intended to use this medical needle device.

A medical needle device disclosed by the assignee of this patent application (see U.S. Patent No. 4,657,535) is well known as the one capable of guaranteeing its tamperproof (which means that the fact that the medical needle device was once used can be recognized later) and its sanitation. This medical needle device comprises a hub for supporting the base of a hollow needle and connecting a connection tube to the hollow needle, and a protector closed at its front end but opened at its base and serving to cover and seal the hollow needle exposed from the hub. The protector and the hub are connected to each other by a coupler provided with a thin portion which can be broken off. The coupler is connected to the protector and the hub by its blocking (which means that two members are bonded to each other by heat created at the time of heat treatment, for example heat sterilization, without using solvent, adhesive or the like). In the case where this medical needle device is to be used, the thin portion of the coupler is broken off and the protector is thus detached from the hub to expose the hollow needle outside. Therefore, the broken coupler teaches that the medical needle device was once used, thereby guaranteeing the medical needle device to be tamperproof.

When the coupler is once broken off to expose the hollow needle outside the protector in the case of this medical needle device, however, the hollow needle cannot be again housed in the protector not to easily get out of the protector. After the medical needle device is used, therefore, it is often disposed with its hollow needle exposed outside. This makes its disposing work very dangerous. Almost all of the medical needle devices which were once used are disposed without being used again particularly in these days. Therefore, the amount of these medical needle devices disposed is quite so large that the possibility of making their disposing work dangerous can be increased.

The present invention is therefore intended to eliminate the above-mentioned drawbacks.

Accordingly, the object of the present invention is to provide a medical needle device guaranteed to be tamperproof and sanitary and capable of housing a hollow needle again in a protector not to easily get out of the protector even after the medical needle device is once used. The object of the present invention is also to provide a medical apparatus intended to use the medical needle device.

The object of the present invention can be achieved by a medical needle device comprising a hollow needle, a hub for supporting the base of the hollow needle, a protector for covering and sealing the hollow needle projected from the hub, an opening means for liquid-tightly integrating the protector with the hub and separating them from each other when the opening means is broken off, and a connecting means arranged on at least one of the protector and the hub to connect them after the opening means is broken off.

According to an aspect of the present invention, the opening means is a breakable thin portion of a coupler, and the coupler is formed separately from the protector and the hub and it is bonded to them. The connecting means is a pipe-like member provided around the coupler, and the pipe-like member is fixed to one of the protector and the hub and it can be fitted onto that portion of the coupler which remains on the other of the protector and the hub, after the thin portion of the coupler is broken off.

According to another aspect of the present invention, the pipe-like member is made of such material that does not adhere to the coupler when the medical needle device is heat-sterilized. The coupler is made of one or more material selected from a group consisting of vinyl chloride resins, polycarbonate and MBS resin, and the pipe-like member is made of polycarbonate. It is more preferable that the coupler is made of polyvinyl chloride.

A medical apparatus according to the present invention comprises the above-described medical needle device, a tube communicated with the hollow needle through the hub, and a container connected to the tube to contain liquid or the like therein.

In the case of the medical needle device, the protector is separated from the hub by the opening means and the hollow needle thus exposed outside from the protector is used. After it is used, the hollow needle is again housed in the protector while the protector is connected to the hub by the connecting means not to be easily disconnected from the hub. The medical needle device can be therefore guaranteed to be tamperproof and sanitary. Even after it is used, the hollow needle can be again housed in the protector not to easily get out of the protector. This can keep workers safe while they are disposing the used medical needle devices.

When the connection means is a pipe-like member arranged round the coupler which is provided with a thin portion, the protector can be

easily fitted onto the hub after it is separated from the hub. Further, if the pipe-like member is made of such material that is not blocked to the coupler at the time when the medical needle device is heat-sterilized, the thin portion of the coupler can be easily broken off to easily separate the protector from the hub.

When the medical apparatus is provided with the above-described medical needle device, its disposing work can be made safe.

This invention can be more fully understood from the following detailed description when taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a side view showing an example of the medical needle device according to the present invention half-sectioned along the longitudinal axis of the device;

Fig. 2 is a side view, half-sectioned, showing the center portion of the medical needle device enlarged;

Fig. 3 is a side view, half-sectioned, showing a hub with a hollow needle, and a protector separated from each other in the medical needle device shown in Fig. 1;

Fig. 4 shows a medical apparatus into which the medical needle device of the present invention is incorporated;

Fig. 5 is a side view showing the hub with the hollow needle just put back into the protector after it is used and;

Fig. 6 is a side view showing the hub with the hollow needle housed in the protector after it is used.

In Fig. 1, a medical needle device 1 comprises a hub 3 for supporting a hollow needle 2, a protector 4 in which the hollow needle 2 projected from the hub 3 is sealed, a breakable coupler 5 liquid-tightly arranged between the protector 4 and the hub 3, and a pipe member 6 attached to the protector 4.

A base 2b of the hollow needle 2 which has a sharp tip 2a is fixed to one end of the hub 3 by adhesive 7 such as epoxy resin. A ring-shaped recess 3a and a protrusion 3b are formed on the other end of the hub 3 and a tube 8 is connected to these ring-shaped recess 3a and protrusion 3b of the hub 3. The hollow needle 2 is thus communicated with the tube 8.

That portion of the hollow needle 2 which is projected from the hub 3 is covered and sealed by the protector 4. The coupler 5 is interposed between the hub 3 and the protector 4, as described above, to liquid-tightly connect them. They are connected to the coupler 5 by blocking at the time of heat (or autoclave) sterilization. Their connection relative to the coupler 5 is made strong by fastening action created by difference between coeffi-

cients of their thermal expansion.

As shown in Fig. 2, the coupler 5 is a pipe-like member provided with a thin portion 9 extending in the circumferential direction substantially at the center thereof. The coupler 5 is formed separately from the hub 3 and the protector 4. This enables the portion 9 of the coupler 5 to be made accurately thin enough to be easily twisted and broken. One of the pipe-like leg portions 10 extending from the thin portion 9 of the coupler 5 to both sides thereof is fitted into a recess 11 on the front end of the hub 3 while the other into the base 4a of the protector 4. The material which form the leg portions 10 of the coupler 5 is then shrunk by heating process in the course of the heat sterilization to fasten a protrusion 12 of the hub 3 and the base 4a of the protector 4 while adhering to them by its blocking. This guarantees the medical needle device to be liquid-tight.

When the liquid-tightness and tamperproof of the medical needle device are not sufficient only by the fastening and blocking of the coupler 5 relative to the hub 3 and the protector 4, adhesive can be applied between the coupler 5 and the hub 3 and between the coupler 5 and the protector 4. It is preferable in this case to use adhesive of the non-solvent type, particularly more preferable to use adhesive of the UV curing type.

The pipe-like member 6 is fitted onto the coupler 5 to cover substantially the whole of the latter. A flange 6a of the pipe-like member 6 is embedded in a groove 13 between the front end 4a of the protector 4 and the coupler 5 and the pipe-like member 6 is thus fixed to the protector 4. When the thin portion 9 of the coupler 5 is broken to separate the hub 3 provided with the hollow needle 2 from the protector 4 as shown in Fig. 3, therefore, the pipe-like member 6 belongs to the protector 4. After the medical needle device 1 is used, the hollow-needle-attached hub 3 is put back into the pipe-like-member-attached protector 4 and then disposed as it is (see Fig. 6).

The coupler 5, the hub 3 and the protector 4 are connected to one another by their blocking, as described above. Materials of which these components are made are therefore of the type capable of blocking to one another. However, the pipe-like member 6 is attached to and detached from a part of the coupler 5 which is left on the side of the hub 3, as described above. Material of which the pipe-like member 6 is made is of the type capable of not blocking to the coupler 5.

It is preferable that the materials of which the coupler 5, the hub 3 and the protector 4 are made are different in heat shrinking rate and that their blocking is made strong by the difference of their heat shrinking rates. The material of which the hub 3 and the protector 4 are made is of the type not

shrunk by heat. Polycarbonate, resins of the vinyl chloride group and MBS resins can be mentioned to use as the material and it is preferable to select polycarbonate because it is not deformed at the time of the heat sterilization and because it has high heat resistance. The coupler 5 is fitted into the recess 11 of the hub 3 and contacted with the protrusion 12 of the hub 3 and the base 4a of the protector 4. It is therefore needed that the coupler 5 is connected to these components by blocking with its heat shrinkage to guarantee the medical needle device 1 to be liquid-tight and tamperproof. Resins of the vinyl chloride group, polycarbonate and MBS resins can be mentioned as being suitable for use as the material of which the coupler 5 is made. Polyvinyl chloride is more suitable because it can be easily twisted and broken.

The pipe-like member 6 is made of such material that is neither shrunk by heat nor blocked relative to the matter or polyvinyl chloride of which the coupler 5 is made. Polycarbonate can be mentioned, for example.

The tube 8 is made of resin of the vinyl chloride group and its adhesion relative to the hub 3 which is made of polycarbonate, for example, is carried out in such a way that it is fitted into the ring-shaped recess 3a of the hub 3 and that it is blocked to the protrusion 3b of the hub 3 located inside it by heat created at the time of the heat sterilization.

The protector 4 is asked to be transparent because the hollow needle 2 sealed in the protector 4 must be recognized. Polycarbonate is therefore more preferable than polyvinyl chloride. Polycarbonate is difficultly deformed by heat and this makes it more suitable for being used as the material of which the protector 4, usually thin, is made. When polyvinyl chloride is used, it is easily deformed by heat to thereby create the possibility of its damaging the hollow needle 2.

The medical needle device 1 having the above-described arrangement is connected to a blood bag 14 through the tube 8 and used as a medical apparatus 15, as shown in Fig. 4. When the medical apparatus 15 is to be used, the hub 3 and the protector 4 are twisted in reverse directions by fingers to break off the thin ring-shaped portion 9 of the coupler 5. A part of the coupler 5, the protector 4 and the pipe-like member 6 are thus broken off from the hub 3 and that part of the coupler 5 which is left on the hub 3 to thereby expose the hollow needle 2 outside, as shown in Fig. 5. The tip 2a of the hollow needle 2 is stuck into a patient to collect blood from him according to the usual manner. The blood is collected into the blood bag 14 through the hollow needle 2 and the connection tube 8. After the blood thus collected in the blood bag 14 is used up later and the medical

apparatus 15 therefore becomes unnecessary, the hollow needle 2 is housed in the protector 4 and the pipe-like member 6 is fitted onto the hub 3 (see Fig. 6). The medical needle device 1 is thus disposed together with the blood bag 14 and the tube 8.

Claims

1. A medical needle device comprising a hollow needle (2), a hub (3) for supporting the base of the hollow needle (2), a protector (4) for covering and sealing the hollow needle (2) projected from the hub (3), an opening means (9) for liquid-tightly integrating the protector (4) with the hub (3) and separating them from each other when the opening means (9) is broken off, and a connecting means (6) arranged on at least one of the protector (4) and the hub (3) to connect them after the opening means (9) is broken off.

2. The medical needle device according to claim 1, characterized in that said opening means is a breakable thin portion (9) of a coupler (5) and said coupler (5) is formed separately from the protector (4) and the hub (3) and bonded to them.

3. The medical needle device according to claim 1, characterized in that said connecting means is a pipe-like member (6) provided around the opening means (9) and said pipe-like member (6) is fixed to one of the protector (4) and the hub (3) and it can be fitted onto an adjacent portion to the opening means (9) which is left on the other of the protector (4) and the hub (3) after the opening means (9) is broken off.

4. The medical needle device according to claim 2, characterized in that said connecting means is a pipe-like member (6) provided around the coupler (5) and said pipe-like member (6) is fixed to one of the protector (4) and the hub (3) and it can be fitted onto that portion of the coupler (5) which is left on the other of the protector (4) and the hub (3) after the opening means (9) is broken off.

5. The medical needle device according to claim 4, characterized in that said pipe-like member (6) is made of such material that does not adhere to the coupler (5) when the medical needle device is heat-sterilized.

6. The medical needle device according to claim 5, characterized in that said coupler (5) is made of one or more materials selected from the group consisting of vinyl chloride resins, polycarbonate and MBS resin, and said pipe-like member is made of polycarbonate.

7. The medical needle device according to claim 6, characterized in that said coupler (5) is made of polyvinyl chloride.

8. A medical apparatus comprising:

medical needle device including a hollow needle (2), a hub (3) for supporting the base of the hollow needle (2), a protector (4) for covering and sealing the hollow needle (2) projected from the hub (3), an opening means (9) for liquid-tightly integrating the protector (4) with the hub (3) and separating them from each other when the opening means (9) is broken off, and a connecting means (6) arranged on at least one of the protector (4) and the hub (3) to connect them after the opening means (9) is broken off;

a tube (8) communicated with the hollow needle (2) through the hub (3); and

a container (14) connected to the tube (8) to contain a fluid therein.

9. The medical apparatus according to claim 8, characterized in that said opening means is a breakable thin portion (9) of a coupler (5) and said coupler (5) is formed separately from the protector (4) and the hub (3) and bonded to them.

10. The medical apparatus according to claim 8, characterized in that said connecting means is a pipe-like member (6) provided around the opening means (9), and said pipe-like member (6) is fixed to one of the protector (4) and the hub (3) and it can be fitted onto an adjacent portion to the opening means (9) which remains on the other of the protector (4) and the hub (3) after the opening means (9) is broken off.

11. The medical apparatus according to claim 9, characterized in that said connecting means is a pipe-like member (6) provided around the coupler (5) and said pipe-like member (6) is fixed to one of the protector (4) and the hub (3) and it can be fitted onto that portion of the coupler (5) which remains on the other of the protector (4) and the hub (3) after the opening means (9) is broken off.

12. The medical apparatus according to claim 11, characterized in that said pipe-like member (6) is made of such material that does not adhere to the coupler (5) when the medical needle device is heat-sterilized.

13. The medical apparatus according to claim 12, characterized in that said coupler (5) is made of one or more materials selected from a group consisting of vinyl chloride resins, polycarbonate and MBS resin, and said pipe-like member is made of polycarbonate.

14. The medical apparatus according to claim 13, characterized in that said coupler (5) is made of polyvinyl chloride.

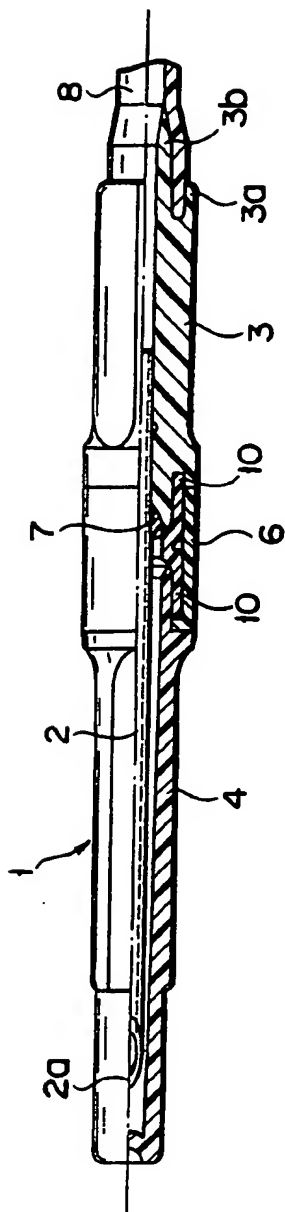


FIG. 1

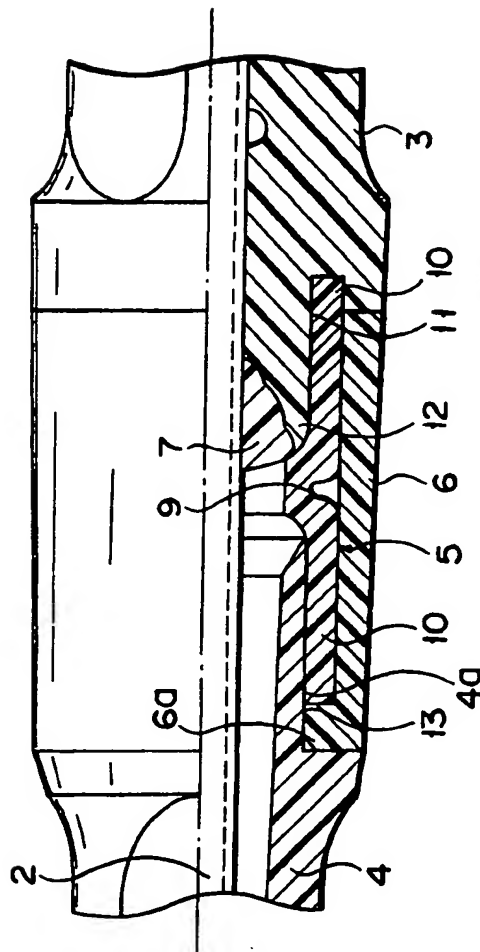


FIG. 2

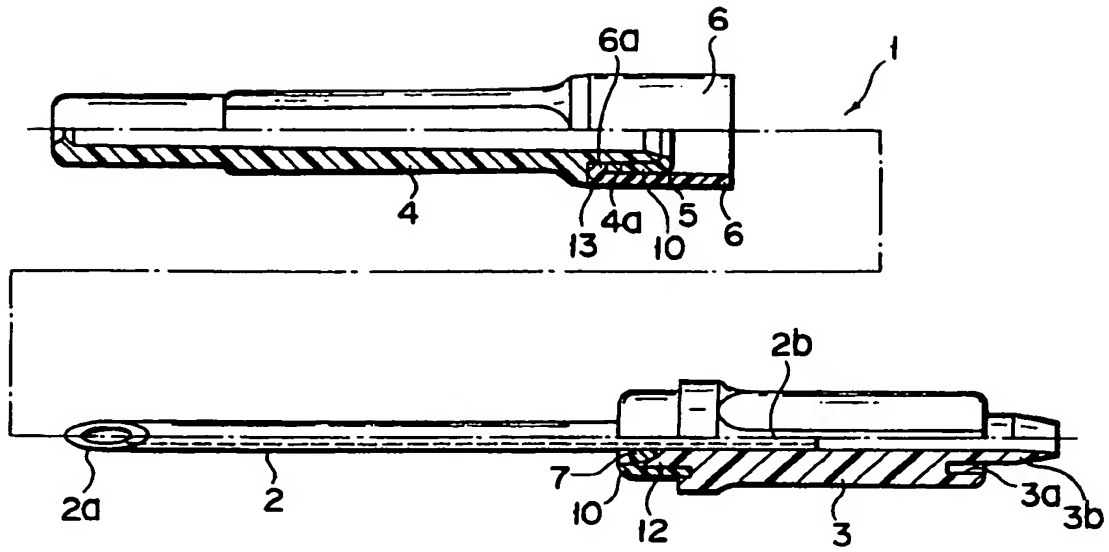


FIG. 3

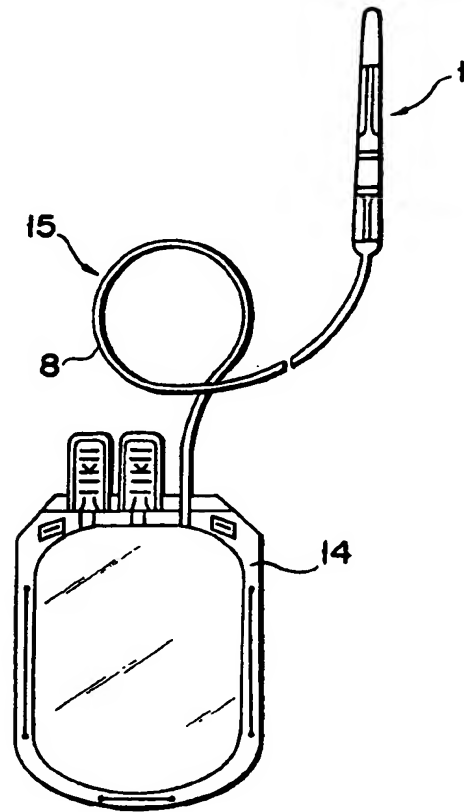


FIG. 4

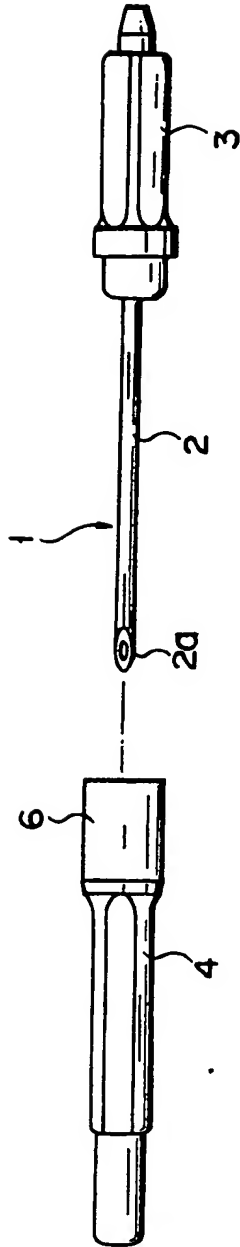


FIG. 5

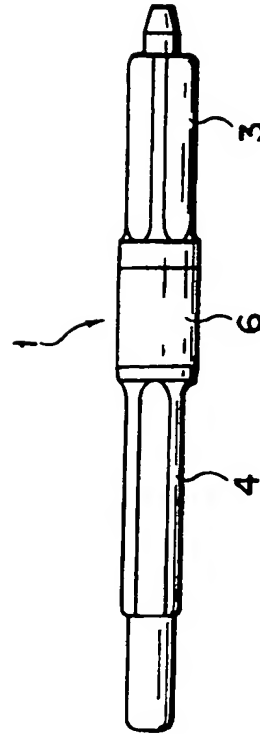


FIG. 6



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EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 90116641.3
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	<u>US - A - 4 508 534</u> (E. GARVER et al.) * Totality; especially fig. 1-6; column 4, lines 54-68; column 5, line 23 - column 7, line 3; column 7, line 42 - column 8, line 48 *	1, 8	A 61 M 5/158 A 61 M 5/32
A	---	3, 10	
D, Y	<u>US - A - 4 657 535</u> (T. NISHIMURA et al.) * Totality; especially fig. 5; column 5, line 54 - column 6, line 11 *	1-14	
Y	<u>US - A - 4 551 138</u> (S. SHINOHARA) * Totality *	1-14	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A 61 M
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 12-12-1990	Examiner LUDWIG
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			